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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,924	08/10/2005	Finn Larsen	20747/250	8593

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EXAMINER

EBRAHIM, NABILA G

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

DETAILED ACTION

Receipt of Information Disclosure Statements filed 3/16/05, and 8/29/05 is acknowledged.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12, 15-27, and 29 rejected under 35 U.S.C. 103(a) as being unpatentable over Aiache et al. US 6210711 (hereinafter Aiache) in view of Estok US 6136818 (hereinafter Estok), and further in view of El-Rashidy US 5770606 (hereinafter El-Rashidy).

Aiache teaches effervescent microspheres (title) microspheres containing an acid substance, a basic substance, and a water-soluble isolating agent which, when it dissolves in water, after almost instant effervescence, brings about a homogeneous dispersion of active principal(s) which is present in the acid and basic substances (abstract). The water-soluble isolating agent whose dissolution in water leads, after almost immediate effervescence, to a solution or a homogeneous dispersion of active principle (col. 2, lines 27-31). The water-soluble isolating agent is in the form of a thin film separating the acidic and alkaline substances (col. 2, lines 38-40). Each microsphere has a three-layer structure: a layer of acidic substance and a layer of alkaline substance separated by a layer of water-soluble isolating agent (col. 2, lines 38-

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43). Aiache disclosed that the pharmaceutical form of the composition may comprise tablets or powder and may comprise excipients (col. 1, lines 20-22).

Aiache also discloses a method for preparing the microspheres by rotational granulation on a fluid air-bed (abstract). The acidic and alkaline powders can also contain diluents, flavorings and sweeteners (col. 4, lines 56-59). With regard to claims 11, 12, 19, and 25, which recite the presence of the active principle inside or outside the microsphere, Aiache teaches that the composition includes a matrix in which the active principle is placed (col. 1, lines 12, and 13), or the active principle may be mixed with the acidic and basic substances, and the adjuvants are mixed together in a fluidized air-bed (col. 1, lines 44-48).

Aiache is deficient in disclosing apomorphine as an active principle, its dosage and uses.

Estok teaches a combination of phentolamine and apomorphine for the treatment of human sexual function and dysfunction. Estok discloses that the typical dosage is about 0.25 to about 6 mg of apomorphine (col. 4, lines 38-44), this dosage encompasses the preferred range recited in claims of the current application as the instant specification discloses that the invention apomorphine is present such that the resulting effervescent formulation contains apomorphine present in a unit dose amount of from between 0.5mg and 50mg, typically 0.5 mg, 1 mg, 1.5mg, 2 mg, 2.5 mg, 3 mg, 3.5 mg, 4 mg, 4.5 mg 5mg, 10 mg, 20 mg, 30 mg, 40 mg or 50 mg. Most preferably the process produces a formulation where apomorphine is present in a unit dose amount of 2 mg to 3 mg (page 13).

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In addition, El-Rashidy teaches in detail the use of apomorphine in sexual dysfunction, the reference teaches that the studies of penile tumescence in male patients afflicted with psychogenic impotence show that while apomorphine can indeed induce an erection in a psychogenic male patient, the apomorphine dose required to achieve a significant erectile response is usually accompanied by nausea or other serious undesirable side effects such as hypertension, flushing and diaphoresis (col. 2, lines 1-10). El-Rashidy adds that sublingual apomorphine dosage forms, usually containing about 2.5 to about 10 milligrams of apomorphine, have been found to be effective in male patients suffering from psychogenic erectile dysfunction without nausea or other undesirable side effects (col. lines 29-34).

Though neither of the references disclosed the very high doses that reach 50 mg as recited in the instant claims, it is the position of the Examiner that adjusting the dosage amount is within the skill of a person skilled in the art and among other factors it mainly depends on the patients needs.

Accordingly, it would have been obvious to one skilled in the art at the time the invention was made to use the multilayered effervescent disclosed by Aiache and expand it with the knowledge taught by either Estok or El-Rashidy to treat sexual dysfunction, the motive would be that Aiache made his invention available to many drugs that can get use the general composition of the multilayer effervescent composition he disclosed and also the motivation would be according to the process for manufacturing microspheres, whether they are two-layer or three-layer microspheres, the powder of alkaline nature, one or more active principles if the latter have alkaline

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properties; whereas the powder of acidic nature may contain one or more active principles if the latter have acidic properties (col. 4, lines 43-55). The expected result would be an effervescent powder or tablet that can be used to treat sexual dysfunction in males and females.

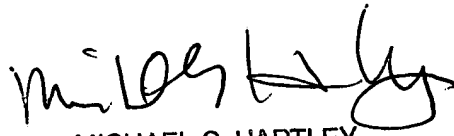
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nabila Ebrahim

4/18/06


MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER